DIAGNOSTIC DEVICES
ACN 119 788 582

K072385

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K072385

Submitter Information (21 CFR 807.92(a)(1))

- **Submitter's Name:** Diagnostic Devices Pty Ltd
- **Submitter's Address:** Suite 405, Westfield Office Tower
  Eastgardens NSW 2036
  Australia

JAN 11 2008

- **Contact Person:** Harry Platt
- **Telephone:** +61 2 8347 2244 Australia
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- **Date Prepared:** 21st August 2007

Name of Device and Classification (21 CFR 807.92(a)(2))

- **Classification Name:** Telephone electrocardiograph transmitter and receiver
- **Common Name:** heartEVENT-AT ECG Recorder with Auto-Trigger
- **Proprietary Name:** heartEVENT^{AT}
- **Product Code:** DXH
- **C.F.R. Section:** 870.2920
- **Classification:** Class II - Performance Standards
- **Classification Panel:** Cardiovascular

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Identification of Legally Marketed Predicate Device (21 CFR 807.92 (a)(3))

- **Predicate Name:** KING OF HEARTS EXPRESS + AF MONITOR
- **Predicate Manufacturer:** CARD GUARD SCIENTIFIC SURVIVAL LTD.
- **Predicate 510(k) Number:** K020825

This legally marketed predicate device was used to determine substantial equivalence in accordance with 21 CFR 807.92(a)(3).

The KING OF HEARTS EXPRESS + AF MONITOR (K020825) is a transtelephonic cardiac event recorder. When an ECG is recorded on the King of Hearts Express AF, the stored ECG it can be transmitted via telephone. Along with being able to record patient-activated events, the recorder also has the ability to detect asymptomatic events with auto-triggers capable of automatically capturing atrial fibrillation, tachycardia and bradycardia.

Device Description (21 CFR 807.92 (a)(4))

- **Device Description Summary:**

The heartEVENT^{AT} is a battery operated transtelephonic ECG event recorder and transmitter that is capable of storing multiple electrocardiograms. The transmission of these recordings is by telephone to a receiving system.

The heartEVENT^{AT} has two operating modes – manual and automatic trigger.

In the manual mode, the heartEVENT^{AT} stores the ECG before and after the 'record' button is depressed. The recording period is preset up to 80 seconds with 2 manually activated recordings stored.

The heartEVENT^{AT} also has an automatic triggering function where recording is automatically activated when the user experiences a cardiac symptom. Cardiac symptoms captured by the auto-trigger function include bradycardia, tachycardia, pause and atrial fibrillation.

The heartEVENT^{AT} is configured with 'pre' and 'post' event memories with a total ECG recording time for up to 320 sec.

The stored ECGs are transmitted by acoustic output by coupling the telephone mouthpiece over the heartEVENT^{AT} by manually depressing the 'send' button.

Intended Use (21 CFR 807.92 (a)(5))

- **Intended Use:**

  The heartEVENT^{AT} is indicated for use by patients as directed by a physician, who experience transient symptoms that may suggest cardiac arrhythmia, conduction abnormalities or other rhythm disturbances that may result in shortness of breath, pre-syncope or palpitations.

- **Precautions and Contraindications for Use:**

  The HeartEVENT^{AT} should be used in accordance with the instructions as indicated in the heartEVENT^{AT} User Manual or as directed by a physician.

  The HeartEVENT^{AT} is contraindicated for use in combination with external cardiac defibrillators or any other high frequency surgical equipment. The patient leads must be disconnected prior to performing any procedure utilizing this equipment.

Similarities to the Predicate (21 CFR 807.92 (a)(6))

- **Substantial Equivalence:**

  The KING OF HEARTS EXPRESS + AF MONITOR (K020825) legally marketed predicate device was used to determine substantial equivalence in accordance with 21 CFR 807.92(a)(3).

  The specifications and characteristics of the predicate device, KING OF HEARTS EXPRESS + AF MONITOR (K020825), were compared to the heartEVENT^{AT}.

  The results of this comparison indicate that the heartEVENT^{AT} has the same or better specifications and characteristics and is substantially equivalent to the KING OF HEARTS EXPRESS + AF MONITOR (K020825).

- **Safety and Effectiveness:**

  The heartEVENT^{AT} utilises similar technology currently found in the legally marketed predicate device. Based on testing and comparison with the predicate device, the heartEVENT^{AT} indicated no adverse indications or results.

  It is our determination that the heartEVENT^{AT} is safe and effective, performing within its design specifications and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

Diagnostic Devices, PTY, Ltd.,
c/o Mr. Harry Platt
Project Manager
Suite 405, Office Tower Westfield Eastgardens
Eastgardens, NSW 2306
AUSTRALIA

Re: K072385
Trade/Device Name: HeartEVENT^{AT} ECG Event Recorder with Auto-Trigger
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: January 2, 2008
Received: January 7, 2008

Dear Mr. Platt:

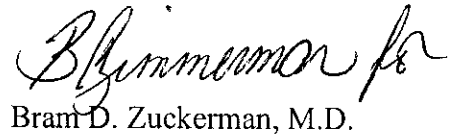
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

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Applicant: Diagnostic Devices Pty Ltd

510(k) Number (if known): K072385

Device Name: heartEVENT^{AT}

Indications for Use:

The heartEVENT^{AT} is indicated for use by patents as directed by a physician, who experience transient symptoms that may suggest cardiac arrhythmia, conduction abnormalities or other rhythm disturbances that may result in shortness of breath, pre-syncope or palpitations.

Contraindications for Use:

The HeartEVENT^{AT} is contraindicated for use in combination with external cardiac defibrillators or any other high frequency surgical equipment. The patient leads must be disconnected prior to performing any procedure utilizing this equipment.

Prescription Use ___✔___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072385